Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The assessment effect of aerobic training program on serum transaminases' levels and quality of life in patients with Non-Alcoholic Steatohepatitis

Protocol summary

Summary

The purpose of this study program of aerobic exercise on serum transaminase and trance is the quality of life in patients with alcoholic steatohepatitis.Thirty NASH patients with the range of age 18 to 65 years old that randomly they were divided in two groups of diet (n=15) and aerobic training with diet (n=15).Patients with inclusion criteria: 1 - 18 to 65 years 2 - Approval Kbdchrb ultrasound 3 - Increase 5 / 1 Equity serum enzyme alanine aminotransferase (ALT) and Exclusion criteria: 1 - Hepatitis B2-hepatitis C 3 - autoimmune hepatitis 4 - CD 5 - Wilson 6 - 1α-deficient anti ¬ trypsin 7 - Hemochromatosis 8 - 9 thyroid disease - ischemic heart disease 10 - 11 of kidney failure - drugs Hpatvtvksyk 12 - more than 20 grams of alcohol per day were enrolled. Anthropometric indices, serum liver enzymes and biochemical factors were evaluated before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104286319N1**
Registration date: **2011-08-27, 1390/06/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-27, 1390/06/05

Registrant information

Name

Hamidreza Sima

Name of organization / entity

Mashhad University of Medical Scienses

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2010-09-22, 1389/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment effect of aerobic training program on serum transaminases' levels and quality of life in patients with Non-Alcoholic Steatohepatitis

Public title

The Effect of Exercise and nutrition on fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18 to 65 years ; Approval Kbdchrb ultrasound; Increase 1.5 Equity serum enzyme alanine aminotransferase. Exclusion criteria: Hepatitis B2; Hepatitis C; Autoimmune hepatitis; CD; Wilson; 1α-deficient anti-trypsin; Hemochromatosis; thyroid disease; Ischemic heart disease; kidney failure; Drugs Hpatvtvksyk; More than 20 grams of alcohol per day.

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
School of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square
City
Mashhad
Postal code
9177948564
Approval date
2011-03-12, 1389/12/21
Ethics committee reference number
89878

Health conditions studied

1

Description of health condition studied
Non Alcoholic Steatohepatitis
ICD-10 code
K70-K77
ICD-10 code description
Diseases of liver

Primary outcomes

1

Description
ALT
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
Unit U / L, a photometer methods

2

Description
AST
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
Unit U / L, a photometer methods

3

Description
FBS
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
mg/dL

4

Description
Insulin
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
mIU/mL

5

Description
Chol
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
mg/dL

6

Description
LDL
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
mg/dL

7

Description
HDL
Timepoint
Before the intervention, two months after the start and

end of three months
Method of measurement
mg/dL

8

Description
VLDL
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
mg/dL

9

Description
TG
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
mg/dL

10

Description
Weight
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
gram

11

Description
BMI
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
Kg/M2

12

Description
WC
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
Cm

13

Description
WHpR
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
%

14

Description
WHtR
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
%

15

Description
HC
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
Cm

16

Description
PBF
Timepoint
Before the intervention, two months after the start and end of three months
Method of measurement
Body Composition

17

Description
Quality of life
Timepoint
before and after intervention
Method of measurement
SF-36 Standard questionnaire

Secondary outcomes

1

Description
Height
Timepoint
Before the intervention, two months later and after three months
Method of measurement
Cm

Intervention groups

1

Description
Diet with aerobic training program
Category
Treatment - Devices

2

Description

Diet alone

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Center of Liver researches, Department of Internal Hospital, Imam Reza Mashhad

Full name of responsible person

Dr Hamid Reza Sima

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Hamid Reza Sima

Street address

School of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Nematy

Position

Assistant Professor in Clinical Nutrition

Other areas of specialty/work

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Full name of responsible person

Dr Hamid reza Sima

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Advanced Hepatology Fellowship

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty